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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE 13 395/35 02/22/00 HOUSEY 09/510,562 **EXAMINER** HM22/1010 SAUNDERS, D Kenyon & Kenyon ART UNIT PAPER NUMBER One Broadway New York NY 10004 1644 DATE MAILED: 10/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 510,562 Applicant(s)

4.3700H

Group Art Unit

SAUNDERL --- The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address---Period for Response A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely. - If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication . - Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). **Status** 7/11/00 & 7/13/00 ☐ This action is FINAL. ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 1 1; 453 O.G. 213. **Disposition of Claims** _____ is/are pending in the application. is/are withdrawn from consideration. □=Claim(s). 36-37,39-40,43-50,52-57 is/are rejected. is/are objected to. Claim(s) are subject to restriction or election requirement. Application Papers See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The proposed drawing correction, filed on ______ is __approved __ disapproved. The drawing(s) filed on______ is/are objected to by the Examiner. The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d). ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received. □ received in Application No. (Series Code/Serial Number) □ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)). *Certified copies not received:__ Attachment(s) Information Disclosure Statement(s), PTO-1449, Paper No(s). ____ □ Interview Summary, PTO-413 Notice of References Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152 Notice of Draftsperson's Patent Drawing Review, PTO-948 □ Other__

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The amendment of 7/11/00 has entered no new matter. Claims 33-58 are pending.

The terminal disclaimer filed 7/13/00 has been accepted.

Upon further consideration by the examiner, prosecution has been reopened. An action on the merits follows.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The disclosure is objected to because of the following informalities:

At page 1, complete continuation data is required that indicates the current status of each parent. The record has no directions to enter any insertion of such data.

Appropriate correction is required.

Claims 48 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 48 and 57 "the first test cell" and "the second test cell" lack antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-34, 36-37, 39-40, 43-50 and 52-57 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams et al (6,043,211) or Escobedo et al (6,110,737).

The two references are both related to US application 07/151,414, which is related to EP 0,327,369, of record.

These teach mammalian cells transfected with a PDGF receptor expression construct (vector with expression promoters, selectable markers, etc.). These cells thus over express a receptor protein of interest. They can be used to evaluate a candidate drug's (agent's) ability to function as an agonist or antagonist (subgenuses of activators and inhibitors) of PDGF (ligand of the over expressed protein). The response can be evaluated in terms of a phenotypic response (cell division as measured by DNA synthesis) and compared to control cells in the presence or absence of PDGF. See Williams et al at col. 39 and Escobedo et al at col. 5. These teachings were contained in application 07/151,414 (copy made of record at interview of 9/12/00). The 2/2/88 filing date must thus be antedated.

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Independent claims 33, 39, 43 and 52 are rejected since the over expressed PDGF receptor is clearly a protein and also an enzyme, by virtue of its C-terminal domain having tyrosine kinase activity.

The limits of dependent claims 34, 40, 44-47, and 53-56 are taught or suggested to one of ordinary skill by the references. Claims 48 and 57, as far they are understood with terms lacking antecedent basis, are also consistent with the teachings. The limits of claims 36-37 and 49-50 would have been inherent (anticipated) or conventional (obvious) in any program to screen potential agents for agonist or antagonist activity.

It is to be noted from the record of the interview of 9/12/00 that applicant considers the instant claims to be directed to screening for activators or inhibitors of the over expressed protein of interest, while the Williams et al reference is directed to screening for activators or inhibitors of the ligand of the over expressed protein. The examiner is unconvinced that the latter situation is outside of the scope of applicant's invention, given the instant disclosure of screening for agonists or antagonists of insulin, which would be the ligand of an over expressed insulin receptor protein. See specification pages 18 and 44-48. Particularly note that page 47, lines 11-12 provide the heading "Screening Assay to Detect Activators and Inhibitors of the Insulin Receptor".

Immediately thereafter, at lines 17-18 applicant refers to screening for insulin (i.e. the ligand) agonists and antagonists.

Dependent claims 35, 38, 41-42, 51 and 58 are objected to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D. whose telephone number is (703) 308-3976.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Typed 10/6/00 DAS

DAVID SAUNDERS PRIMARY EXAMINER ART UNIT 182 /6 ccc

David a Saunden